



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/622,575

07/21/2003

Nils-Gunnar Holmer

150-126

3373

7590

01/04/2007

Steven S. Payne
8027 ILIFF Drive
Dunn Loring, VA 22027

EXAMINER

CHENG, JACQUELINE

ART UNIT

PAPER NUMBER

3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

01/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/622,575	Applicant(s) HOLMER, NILS-GUNNAR	
	Examiner Jacqueline Cheng	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/9/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed August 9, 2006 with respect to claims 23-28 have been fully considered but they are not persuasive. Applicant argues that US Patent No. 6,060,943 (hereinafter Slayton) does not disclose that the condition of the tissue is controlled between therapeutic pulses, nor are the waves pulsed. The examiner respectfully disagrees with the applicant, although true Slayton does cite in the abstract that "the imaging, therapeutic heating and temperature monitoring of the treatment region can be conducted substantially simultaneously" it does not cite that it is the only way nor does it cite that it is done at exactly simultaneously, just substantially simultaneously. In fact Slayton does disclose that the acoustic transducer of the ultrasonic system sends out acoustic pulses (col. 2 line 63-65, col. 5 line 64-col. 6 line 5) and also that the region is interrogated substantially immediately after the region is heated by the acoustic pulsed waves, therefore being between the therapeutic pulses (col. 7 line 55-67, col. 8, line 55-col. 9 line 10).
2. Applicant's arguments with respect to claim 15-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3768

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 23-27 are rejected under 35 U.S.C. 102(a) as being anticipated by US Patent No. 6,060,943 (herein referred to as Slayton et al).

5. **Claims 23-25:** Slayton et al. discloses an ultrasonic system useful for imaging, therapy, and temperature monitoring. The ultrasonic imaging sends ultrasonic waves (diagnostic energy) into the body and generates an image, from the echo pulses returned, of the treatment region to assist the user in positioning the transducers to the treatment region. The ultrasonic therapy performs, through an acoustic transducer, therapeutic heating through the skin to the target tissue (abstract). This transducer includes a ceramic plate and other related components that are coupled to the target tissue via a fluid circulating between the acoustic matching layer and an acoustically-transparent membrane. This fluid acts as a coolant for the ceramic plate and the acoustic matching layer and also aids in controlling the temperature of the tissue at the interface. Slayton et al. also discloses temperature control for the circulating fluid, such as a thermoelectric cooling module or any other such device (col. 6 line 52-64). The transducer is controlled by drivers that steer, and/or focus the waves to the region of interest in the target tissue. The heating power and time are also controlled to provide the proper heating pattern and therapeutic dosage (col. 7 line 45-54). The amount of heat generated can be detected by the temperature monitoring subsystem. This subsystem sends out an acoustic pulse wave to a certain boundary such as the boundary between tissue and air (the contact surface) (col. 9 line 46) and then reads the temperature from the reflected echoes (col. 8 line 55-col. 9 line 10).

Art Unit: 3768

6. **Claim 26 and 27:** Slayton et al. discloses that the emitted acoustic waves of the therapeutic ultrasound can be pulsive in the time domain, emitting energy in periods spaced by pauses (col. 5 line 64-col. 6 line 6).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Slayton et al. as applied to claim 23 above, and further in view of US Patent No. 6,488,626 B1 (herein referred to as Lizzi). Lizzi discloses using an ultrasonic therapeutic system along with a diagnostic ultrasound system to monitor tissue motion. In the invention a continuous sequence of diagnostic pulses in which therapeutic pulses are pulsed. Following exposure to the therapeutic ultrasound beam, the diagnostic ultrasound echoes are again recorded (col. 4 line 65-col. 5 line 22). It would be obvious to one skilled in the art at the time of the invention to combine Lizzi with Slayton as the steps of analyzing tissue characteristics and taking diagnostic pulses in between therapeutic pulses can be applied to any type of ultrasonic therapy. Both Lizzi and Slayton claim inventions on the topic of ultrasonic therapy on tissue and diagnosing the tissue.

Art Unit: 3768

9. **Claims 15-17, 29, and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent No. 2001-61874 (herein referred to as Sato) in view of US Patent No. 4,483,343 (herein referred to as Beyer). In the abstract Sato discloses a cooling element such as a water bag for circulating cooling water as a heating exchange element between the an ultrasonic vibrator and an organism. Although it does not say in the abstract of Sato whether the water bag can be exchangeable or not, it would be obvious to have a detachable, exchangeable bag as it is well known in the art, as can be seen by Beyer. Beyer discloses an ultrasonic apparatus comprising a liquid sack which is capable of being attached or detached as desired. The sack can also be inflated or deflated which will vary the position of the transducers depending on what location of the target area is to be scanned or treated (col. 1 line 65-col. 2 line 15). It would be obvious to one skilled in the art at the time of the invention to combine the teachings of Sato and Beyer as to be able to have a detachable bag to be able to change the scanning depth of the ultrasound waves.

10. **Claims 18 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato in view of Beyer as applied to claim 17 above, and further in view of US Patent No. 5,590,653 (herein referred to as Aida). Aida discloses a water bag in which the temperature of the fluid can be both measured as well as controlled. A control circuit controls the cooling device to set the temperature the water is to be cooled to (col. 16 line 6-17).

11. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato in view of Beyer as applied to claim 15 above, and further in view of US Patent No. 5,984,881 (herein referred to as Ishibashi). Ishibashi discloses an ultrasound therapeutic apparatus that

Art Unit: 3768

consists of a therapeutic ultrasonic wave generator and an imaging probe. The imaging probe is used to receive echoes of the ultrasonic pulses. The driving conditions for the therapeutic ultrasonic wave generating source is then adjusted on the basis of the received echo signal (abstract). The system is capable of forcibly stopping the therapy so the system is capable of adjusting the therapeutic waves to stop based on the echo signals of the tissue. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Ishibashi with Sato and Beyer as it is important to know when to stop and start therapy depending on the conditions of the tissue.

12. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato in view of Beyer in view of Ishibashi as applied to claim 20 above, and further in view of US Patent No. 6,858,006 B2 (herein referred to as MacCarter). MacCarter discloses a system for monitoring health information of patients. This system includes an ultrasonic sensor that can emit sound waves from the skin's epidermal layer to a distal portion and then calculate the reflection transit time as a correlation to tissue thickness (col. 13 line 5-13). It would be obvious to combine MacCarter with Sato, Beyer and Ishibashi as the echoes of the ultrasonic wave are already collected it is just a matter of processing the information, the information of tissue thickness would be an obvious thing to need or want in order to know how deep to scan the ultrasonic waves.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER